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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
07/402,450	09/01/1989	GEORGE J. MURAKAWA	2124-154	8131
6449 7590 12/23/2008 ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005				
EXAMINER CHUNDURU, SURYAPRABHA				
ART UNIT 1637		PAPER NUMBER		
NOTIFICATION DATE 12/23/2008		DELIVERY MODE ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

## Office Action Summary

**Application No.**

07/402,450

**Applicant(s)**

MURAKAWA ET AL.

**Examiner**

Suryaprabha Chunduru

**Art Unit**

1637

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 190-234 and 242-255 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 190-234, 242-255 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

**DETAILED ACTION**

1. Applicants' response to the office action filed on September 17, 2008 has been considered and acknowledged.

***Status of the application***

2. Claims 190-234, 242-255 are pending. Claims 1-151 were canceled. New claim 249-255 were added. All the arguments and the amendment were fully considered and found persuasive in-part. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. The action is made FINAL.

***Response to arguments:***

3. With regard to the arguments on the priority issue, Applicants' arguments were fully considered and were found unpersuasive. Applicants argue that the use of same oligonucleotides have support in the earlier filed applications and indicate that the earlier filed application 07/148,959 (hereafter '959) filed on January 1988 for support for the said limitation. Applicants' arguments and the cited paragraph of the priority application '959 were fully considered. After reviewing the patent application '959 and the cited paragraph, and the preceding paragraphs on page 3 of the specification of patent application '959, it is noted that the reference RNA in the cited paragraph is referring to a beta actin gene, and not to the reference maxigene as asserted by the Applicants. Examiner further notes on page 7 of the specification of patent application '959 use of a separate primer for maxigene amplification (see example III of the patent application '959 on page 7). Accordingly the limitation 'same oligonucleotides' does not have support in the earlier filed application '959 and the instant application does not get the priority back to January 27, 1988.

4. With regard to the rejection of claims 114-248 under 35 USC 112, second paragraph, Applicants' arguments and the amendment were fully considered and the rejection is withdrawn herein in view of the amendment deleting the limitation 'are of similar length'.

5. With regard to the rejection of claims 114-115, 117-118, 120, 122-123, 125-126, 128, 130-131, 133-134, 136, 138, 141-142, 144, 146-151, 190-192, 194-195, 197, 199-201, 203-204, 206, 208-210, 212-213, 215, 217-219, 221-222, 224, and 226-248 under 35 USC 135(b) as being anticipated by Wang et al., Applicants' arguments and the amendment were fully considered and found unpersuasive. Applicants' arguments were found unpersuasive. Applicants argue that the instant claims do not require the use of a shared primer pair and assert that the rejection should be withdrawn. Applicants' arguments were fully considered and found unpersuasive. The instant claims recite 'can be amplified by the same oligonucleotides or by the different oligonucleotides', which clearly state that the shared primer pair is required and Wang et al. reference does teach the use of shared or same primer pair.

With regard to the new claims 249-255, Applicants argue that the Wang et al. reference is not applicable as a prior art because based on the amendment filed on 6 December, 2007, the Board concluded that the instant claims do not require the use of the shared primer pair. Applicants' arguments based on the Board decision were fully considered. However the instant new claims as presented now clearly recite use of the same oligonucleotides to amplify both reference and viral RNA target and accordingly Wang et al. reference is applicable. Applicants further assert that the final, step in claims 249-252 recite determining the relative amounts of target viral RNA, which the Board noted as different than the corresponding step of Wang et al. reference. Applicants' arguments were fully considered and found unpersuasive because the steps

preceding to the final step are not different from that of the corresponding steps of Wang et al. reference thus the method steps as presented does inherently teach determining relative amounts of the target viral RNA in comparison to the reference RNA sequence. Accordingly the rejection is maintained and the rejection includes new claims 249-255 and the text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. The rejection is moot for claims 234-241 in view of the Amendment canceling said claims.

6. With regard to the rejection of claims 116, 119, 121, 124, 127, 129, 132, 135, 139, 140, 143, 145, 193, 196, 198, 202, 205, 207, 211, 214, 220, 223 and 225 under 35 USC 135(b)(1) over Wang et al. in view of Mullis et al., Applicants' arguments and the amendment were fully considered and found unpersuasive. Applicants' argue that the claims as presented now are not directed to the same subject matter as of Wang et al. and Wang et al. reference is not a prior art and the rejection should be withdrawn. As discussed above the claims as presented now still encompass the same subject matter and the claims are obvious over Wang et al. in view of Mullis et al. as discussed in the rejection and thus the rejection is maintained herein.

### ***Conclusion***

No claims are allowable.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Suryaprabha Chunduru/

Primary Examiner, Art Unit 1637